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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

World Trade Center Health Program Enrollment, Appeals, Reimbursement and Certification - New - National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act), promulgated on December 22, 2010, establishes a Federal program to support health monitoring and treatment for emergency responders; recovery and cleanup workers; and residents, building occupants, and area workers in New York City who were directly impacted and adversely affected by the terrorist attacks of September 11, 2001. In order to provide medical monitoring and treatment to eligible individuals, the World Trade Center (WTC) Health Program will collect eligibility and appeals data as well as information from medical and prescription pharmaceutical providers.

All responders to the New York City attack who will be newly seeking medical monitoring and treatment and survivors of the attack who were not covered by the Medical Monitoring and Treatment Program (MMTP) (for responders) or the Community Program (for survivors) prior to January 2, 2011, may apply to obtain coverage under the new WTC Health Program. In order to begin the determination eligibility process, an enrollment form must be completed. After an eligibility application is submitted to the Program, an unsuccessful applicant has an opportunity to appeal the decision; enrolled participants have further appeal rights. Health care and prescription pharmaceutical providers will be required to submit medical determinations to the WTC Program Administrator and request reimbursement.

Data are being collected in order to determine the eligibility of applicants. If an applicant is denied enrollment based on the information provided, the applicant will receive a letter that gives the reason for the denial and the opportunity to appeal the decision.

Once someone is enrolled, he or she may request approval for reimbursement of travel if the individual must travel more than 250 miles to receive healthcare services.

Healthcare providers and pharmacies will file claims electronically or by paper form to be paid for their services. There are three separate enrollment forms for each population of responders (Fire Department of New York City responders, general responders, and survivors). The following information includes the definition of each population:

``FDNY responder`` is defined as a member of the Fire Department of New York City (whether fire or emergency personnel, active, or retired) who participated at least one day in the rescue and recovery effort at any of the former World Trade Center sites.

``General Responder`` is a worker or volunteer who provided Rescue, Recovery, Demolition, Debris, Removal and related support services in the aftermath of the September 11, 2001

attacks on the World Trade Center but was not affiliated with the Fire Department of New York.

``Survivor'' is a person who was present in the disaster area in the aftermath of the September 11, 2001 attacks on the World Trade Center as a result of his or her work, residence, or attendance at school, childcare, or adult daycare.

The eligibility application form will collect general contact information as well as information regarding the WTC disaster area experience. Some of the information provided will be shared with the Federal Bureau of Investigation in order to screen an individual against the terrorist watch list maintained by the Federal government. This information will also be shared with the WTC Program Administrator and will be kept in a secure manner.

WTC Health Program applicants and enrolled participants have opportunities to appeal adverse decisions made by the WTC Program Administrator. The first opportunity to appeal arises after a determination that an applicant does not meet the eligibility requirements.

Once enrolled in the Program, participants will also have the opportunity to appeal a decision not to certify a WTC-related health condition or a determination that treatment will not be authorized as medically necessary. In the notification letter explaining the adverse determination, the applicant will be advised that an appeal can be requested by submitting in writing his or her name, contact information, and an explanation for the basis of the appeal.

Certain enrolled participants may be reimbursed for necessary and reasonable transportation and expenses incident to the securing of medically necessary treatment through the nationwide network if the care involves travel of more than 250 miles. Individuals requesting reimbursement must fill out a 1-page written form requesting such information as date of travel, distance, and total expense.

Pharmacies will transmit reimbursement claims to the WTC Health Program. The following data elements will be collected for pharmacy reimbursement: Pharmacy name, pharmacy address, drug name, prescription number, patient name, patient ID number, and cost. Pharmacies utilize Electronic Data Interchange (EDI) processing at the point-of-sale to transmit claims to the World Trade Center Health Program (WTCHP). The EDI transmission

conforms to ANSI standards developed by the National Council for Prescription Drug Programs. The information collection burden occurs as the WTCHP member information is copied from the membership card at the point-of-sale. The EDI transmission occurs in real-time as the prescription transaction is made.

The Zadroga Act of 2010 requires that all qualifying WTC-related health conditions or health conditions medically associated with a WTC-related health condition be certified by member to enable reimbursement of treatment services for care rendered to that member for a given qualifying condition(s). To meet the requirement for certification and maintain continuity of care for an individual who had been enrolled in the prior MMTP or Community Program, the WTC Health Program physician shall attest that a prior determination was rendered in the previous federally sponsored program. The attestation will include the physician's name and signature, the name of the patient, and the name of the health condition and its diagnostic (ICD-9) code.

An individual who is new to the WTC Health Program must have a certified WTC-related health condition or health condition medically associated with WTC-related health condition to receive reimbursement for treatment and other services. If a new medical determination is being made, the Program clinician must

provide to the WTC Health Program the patient's name and program identification number, the name and diagnostic code of the health condition, and a brief narrative explaining the key exposure findings. The narrative will include information such as the time and duration of the individual's presence in defined geographic areas (of exposure), whether the individual was caught in the dust cloud on September 11, 2001, whether the individual conducted strenuous activity while in the exposure zone(s), the individual's symptom time course relative to September 11, 2001, and the reasons a person might be more likely to get sick from given exposures (family history or coexisting medical problems).

A Program physician will also submit a form to the WTC Health Program when a member needs medical treatment for a condition that has not yet been certified. In that case, the physician will request authorization to treat the condition because of the urgency of the medical scenario. The physician will sign a form attesting that a determination was made, and indicate the patient's name and the name of the health condition and its diagnostic code. Physicians will be compensated through administrative expenses invoiced by their respective Clinical Center of Excellence that is under contract with the Federal

government. There are no costs to respondents other than their time. The total estimated annual burden hours are 19,161.

Estimated Annualized Burden Hours

Currently Identified Responders and Currently Identified Survivors: HHS estimates that approximately .5 percent of responders and survivors who had been enrolled in the prior MMTP or Community Program (currently identified responders and survivors), or 290, will be asked to provide the Program with additional information to ensure that the individual meets all criteria to be eligible for the program. There is no form associated with this request. Rather, the Program staff will collect the information provided and make a note of it in the patient files. We expect that responding to this inquiry to take no more than 10 minutes.

World Trade Center Health Program Eligibility Application: Three different eligibility forms were developed to address the different criteria for each group covered by the WTC Health Program: Fire Department of New York responders, general responders, and survivors. We expect that to receive approximately 4,728 applications per year. The burden table reflects the annualized total burden broken into the three separate applicant groups: we estimate that 189 Fire Department of New York (FDNY) responders (4% of applicants); 2,979 general responders (63%); and 1,560 survivors (33%) will submit written applications. The burden estimates for these three different forms are: FDNY responders = 95 hours; general responders = 1,490 hours; and survivors = 390 hours.

Denial Letter and Appeal Notification -- Eligibility: Of the 4,728 applications we expect to receive per year, we expect that 10% will fail due to ineligibility. We further assume that 10% of those individuals, or 47 respondents, will appeal the decision. The burden estimate is 24 hours (Attachment F)

Denial Letter and Appeal Notification -- Health Condition: We expect that program participants (enrolled responders and survivors) will request certification for 32,361 health conditions each year. Of those 32,361, we expect that .001% (32) of certification requests will be denied by the WTC Program Administrator. We further expect that 95% of denied

certifications, or 30 individuals, will be appealed. The burden estimate is 15 hours (Attachment G).

Denial Letter and Appeal Notification -- Treatment: Of the projected 19,596 enrollees who will receive medical care, it is estimated that 3 percent (588) will appeal a determination by the WTC Health Program that the treatment being sought is not medically necessary. We estimate that the appeals letter will take no more than 30 minutes. The burden estimate is 294 hours (Attachment H).

WTC Health Program Medical Travel Refund Request: WTC responders or certified eligible survivors who travel more than 250 miles to a nationwide network provider for medically necessary treatment may be provided necessary and reasonable transportation and other expenses. These individuals may submit a travel refund request form, which should take respondents 10 minutes to complete. HHS expects no more than 10 claims per year. The burden estimate is 2 hours (Attachment I).

WTC Health Condition Certification Request: Physicians will report this data electronically and on paper. HHS expects that 2,300 program physicians will spend approximately 30 minutes extracting the required elements from the patient records and transmitting them to NIOSH, and that approximately 32,361 diagnoses, or 14 per provider, will be reported to the WTC Health Program each year. The burden estimate is 16,100 hours (Attachment J).

Outpatient prescription pharmaceuticals: Pharmacies will electronically transmit reimbursement claims to the WTC Health Program. HHS estimates that 150 pharmacies will submit reimbursement claims for 39,192 prescriptions per year, or 261 per pharmacy; we estimate that each submission will take 1 minute. The burden estimate is 653 hours.

Standard Form 3881, for reimbursement for medically necessary treatment, monitoring, initial health evaluations: Standard U.S. Treasury form SF 3881 (OMB No. 1510-0056) will be used to gather necessary information from Program healthcare providers so that they can be reimbursed directly from the Treasury Department. HHS expects that approximately 200 providers and provider groups will submit SF 3881, which is estimated to take 15 minutes to complete. Providers will submit only one SF 3881.

Type of Respondent	Form Name	No.of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Currently Identified Responders and Currently Identified Survivors	No Form	290	1	10/60	48
FDNY Responder	World Trade Center Health Program FDNY Responder Eligibility Application	189	1	30/60	95
General Responder	World Trade Center Health Program Responder Eligibility Application (Other than FDNY)	2979	1	30/60	1490
WTC Survivor	World Trade Center Health Program Survivor Eligibility Application	1560	1	15/60	390
FDNY Responder, General Responder and WTC Survivor	Denial Letter and Appeal Notification - Eligibility	47	1	30/60	24

FDNY Responder, General Responder and WTC Survivor	Denial Letter and Appeal Notification - Health Conditions	30	1	30/60	15
FDNY Responder, General Responder and WTC Survivor	Denial Letter and Appeal Notification - Treatment	588	1	30/60	294
FDNY Responder, General Responder and WTC Survivor	WTC Health Program Medical Travel Refund Request	10	1	10/60	2
Physician	WTC Health Condition Certification Request	2,300	14	30/60	16,100
Pharmacy	Outpatient prescription pharmaceutica ls	150	261	1/60	653
Physician	Standard Form 3881, for reimbursement for medically necessary treatment, monitoring, initial health evaluations	200	1	15/60	50

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Daniel Holcomb
Reports Clearance Officer
Centers for Disease Control and Prevention

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